DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 8, 2015

Medtronic Sofamor Danek USA, Incorporated
Ms. Lila Joe
Principal Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K143019
Trade/Device Name: CD HORIZON® Spinal System, IPC® POWEREASE® System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, OSH, MNH, MNI, KWP, KWQ, HWE
Dated: March 9, 2015
Received: March 10, 2015

Dear Ms. Joe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*CD HORIZON®

510(k) Number *(if known)*

K143019

Device Name

CD HORIZON® Spinal System

Indications for Use *(Describe)*

The CD HORIZON® Spinal System with or without SEXTANT® instrumentation is intended for posterior, non-cervical fixation as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, curvatures (i.e., scoliosis, kyphosis, or lordosis), tumor, pseudarthrosis, and/or failed previous fusion.

Except for hooks, when used as an anterolateral thoracic/lumbar system, the CD HORIZON® Spinal System may also be used for the same indications as an adjunct to fusion.

With the exception of degenerative disc disease, the CD HORIZON® LEGACY™ 3.5mm rods and the CD HORIZON® Spinal System PEEK rods and associated components may be used for the aforementioned indications in skeletally mature patients as an adjunct to fusion. The 3.5mm rods may be used for the specific pediatric indications noted below.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the CD HORIZON® Spinal System implants are indicated as an adjunct to fusion to treat progressive spinal deformities (i.e., scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the CD HORIZON® Spinal System is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis / spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. These devices are to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

The CD HORIZON® SPIRE™ Plate is a posterior, single-level, non-pedicle supplemental fixation device intended for use in the non-cervical spine (T1-S1) as an adjunct to fusion in skeletally mature patients. It is intended for plate fixation/ attachment to spinous processes for the purpose of achieving supplemental fixation in the following conditions: degenerative disc disease (as previously defined), spondylolisthesis, trauma, and/or tumor.

In order to achieve additional levels of fixation, the CD HORIZON® Spinal System rods may be connected to the VERTEX® Reconstruction System with the VERTEX® rod connector. Refer to the VERTEX® Reconstruction System Package Insert for a list of the VERTEX® indications of use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K143019

Device Name
IPC® POWEREASE System

Indications for Use *(Describe)*

IPC® System is indicated for the incision/cutting, removal, drilling and sawing of soft and hard tissue and bone, and biomaterials in Neurosurgical (Cranial, Craniofacial), Orthopedic, Arthroscopic, Spinal, Sternotomy, and General surgical procedures.

The IPC® POWEREASE™ System is indicated for drilling, tapping and driving screws and working end attachments during spinal surgery, including open and minimally invasive procedures. It is also used in placement or cutting of screws, posts and rods.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) SUMMARY

MEDTRONIC Sofamor Danek
CD HORIZON® Spinal System

April 2015

Submitter	Medtronic Sofamor Danek, USA Inc. 1800 Pyramid Place Memphis, Tennessee 38132 Telephone: (901)396-3133 Fax: (901) 346-9738
Contact Person	Lila Joe Principal Regulatory Affairs Specialist Direct Telephone: (901)399-2309
Date Prepared	April 01, 2015
Common Name	1. CD HORIZON® Spinal System: Drivers and Taps 2. MEDTRONIC REUSABLE INSTRUMENTS COMPATIBLE WITH THE IPC® POWEREASE® System: Drivers and Taps
Regulatory Class, Regulation Number, Regulation Name, and Device Product Code	1. CD HORIZON® Spinal System • Class III • 21 CFR 888.3050 Spinal Interlaminal Fixation Orthosis; KWP • 21 CFR 888. 3060 Spinal Intervertebral Body Fixation Orthosis; KWQ • 21 CFR 888.3070 Pedicle Screw System; MNH, MNI, NKB, OSH 2. MEDTRONIC REUSABLE INSTRUMENTS COMPATIBLE WITH THE IPC® POWEREASE® System • Class II • 21 CFR 878.4820: HWE

Regulatory Class, Regulation Number, Regulation Name, and Device Product Code	Note: The subject drivers and taps are part of the CD HORIZON® Spinal System. Therefore, the regulations and product codes for the CD HORIZON® Spinal System are included as listed above.
Predicate Devices	1. CD HORIZON® Spinal System (Primary Predicate) • K141605 CD HORIZON® Spinal System (S.E. 07/14/2014) 2. MEDTRONIC REUSABLE INSTRUMENTS COMPATIBLE WITH THE IPC® POWEREASE® System • K111520 IPC® POWEREASE® System (S.E. 10/26/2011) *The predicates have not been subject to a design related recall.*
Description of Device	1. The CD HORIZON® Spinal System consists of a variety of shapes and sizes of rods, hooks, screws, CROSSLINK® plates, staples and connecting components, as well as implant components from other Medtronic spinal systems, which can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case. 2. MEDTRONIC REUSABLE INSTRUMENTS COMPATIBLE WITH THE IPC® POWEREASE® System The Medtronic Reusable drivers and taps that are compatible with Medtronic's IPC® POWEREASE® System are spine preparation instruments, which are manufactured from materials commonly used in orthopedic procedures which meet available national or international standards specifications. The subject taps and drivers may be connected to the POWEREASE® Driver or used manually if desired. These instruments are also compatible with various Medtronic spinal implant systems.

Indications for Use	1. <u>CD HORIZON® Spinal System</u> The CD HORIZON® Spinal System with or without SEXTANT® instrumentation is intended for posterior, non-cervical fixation as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, curvatures (i.e., scoliosis, kyphosis, or lordosis), tumor, pseudarthrosis, and/or failed previous fusion. Except for hooks, when used as an anterolateral thoracic/lumbar system, the CD HORIZON® Spinal System may also be used for the same indications as an adjunct to fusion. With the exception of degenerative disc disease, the CD HORIZON® LEGACY™ 3.5mm rods and the CD HORIZON® Spinal System PEEK rods and associated components may be used for the aforementioned indications in skeletally mature patients as an adjunct to fusion. The 3.5mm rods may be used for the specific pediatric indications noted below. When used for posterior non-cervical pedicle screw fixation in pediatric patients, the CD HORIZON® Spinal System implants are indicated as an adjunct to fusion to treat progressive spinal deformities (i.e., scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the CD HORIZON® Spinal System is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis/spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. These devices are to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach. The CD HORIZON® SPIRE™ Plate is a posterior, single-level, non-pedicle supplemental fixation device intended for use in the non-cervical spine (T1-S1) as an adjunct to fusion in skeletally

Indications for Use	mature patients. It is intended for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fixation in the following conditions: degenerative disc disease (as previously defined), spondylolisthesis, trauma, and/or tumor. In order to achieve additional levels of fixation, the CD HORIZON® Spinal System rods may be connected to the VERTEX® Reconstruction System with the VERTEX® rod connector. Refer to the VERTEX® Reconstruction System Package Insert for a list of the VERTEX® indications of use. 2. <u>IPC® POWEREASE® System</u> IPC® System is indicated for the incision/cutting, removal, drilling and sawing of soft and hard tissue and bone, and biomaterials in Neurosurgical (Cranial, Craniofacial), Orthopedic, Arthroscopic, Spinal, Sternotomy, and General surgical procedures. The IPC® POWEREASE™ System is indicated for drilling, tapping and driving screws and working end attachments during spinal surgery, including open and minimally invasive procedures. It is also used in placement or cutting of screws, posts and rods.
Comparison of Technological Characteristics with the Predicate Devices	1. <u>MEDTRONIC REUSABLE INSTRUMENTS COMPATIBLE WITH THE IPC® POWEREASE® System</u> The subject Medtronic CD HORIZON® Reusable drivers and taps that are Compatible with the IPC® POWEREASE® System have the same fundamental technology and stainless steel materials as the predicate devices. The Medtronic CD HORIZON® Reusable drivers and taps that are Compatible with Medtronic's IPC® POWEREASE® System are intended for use in surgical procedures to manipulate tissue, bone, or for use with other devices in orthopedic surgery. An instrument may be used for tapping or driving screws. An instrument may incorporate a measuring function which has uses

	as described on the label and the instrument. K111520 IPC® POWEREASE® System
Performance Data	The following performance data were provided in support of substantial equivalence. **Biocompatibility** The subject CD HORIZON® drivers and taps that are compatible with the IPC® POWEREASE® System are instruments manufactured from : • medical grade stainless steel per - ASTM A564, Standard Specification for Hot-Rolled and Cold-Finished Age-Hardening Stainless Steel Bars and Shapes, - ASTM F899, Standard Specification for Wrought Stainless Steel for Surgical Instruments, and - ASTM A693, Standard Specification for Precipitation - Hardening Stainless Steel and Heat Resisting Steel Plate, Sheet and Strip. • Stainless Steel (Custom 465 Stainless Steel or Custom 455 Stainless Steel) • 17-4 Stainless Steel The subject CD HORIZON drivers and taps that are compatible with the IPC® POWEREASE® System are external communicating devices and are classified as limited, up to 24 hours of body contact according to FDA's Draft Guidance for Industry and FDA Staff: Use of International Standard ISO-10993, Biological Evaluation Method Devices Part 1: Evaluation and Testing, issued April 23, 2013.
Conclusion	Based on the risk analysis, and additional supporting documentation provided in the pre-market notification, the subject CD HORIZON® Spinal System is substantially equivalent to the following predicates: • K141605 CD HORIZON® Spinal System (S.E 7/14/2014) • K111520 IPC® POWEREASE® System (S.E. 10/26/2011)